

SITE EVALUATION GAP - CANCER THERAPIES



United States - Confidential Client

PROJECT DESCRIPTION

Hyde performed a thorough gap analysis of the Cleaning Program for a drug product in short supply that was being manufactured at a contract manufacturing facility under consent decree.

Hyde's work on the project involved Hyde Analytical Lab studies, cleaning verification program development and execution as well as cycle development and operational qualification.

SCOPE AND DELIVERABLES

- ✓ Cleaning Process Design of Experiments (DOE) Study
- ✓ Swab Method Validation
- ✓ Surface Swab Recovery Validation
- ✓ Visual Residue Limit Supply

CLEANING VERIFICATION



Surface Area Calculations / Maximum Allowable Carry-over calculations (MAC).



Development of acceptance criteria (and, as applicable, alert and action limits) for cleaning.



Statistical Analysis technical reports of data gathered during verification



Protocol development, execution, and summary reports.

REQUIREMENTS PURE STEAM GENERATOR							
URS REQ #	DESCRIPTION	QRA	FAT	SAT	IQ	OQ	PQ
2	OPERATIONAL REQUIREMENTS						
2.1	Capacity						
1	CSG stand for NL T 5000 lbs/hr with 3.0-4.3 Bar clean steam pressure distribution, and NSMT 8 Bar plant steam pressure at equipment	NCOP	DOC	TEST			
2	Supply Clean Steam to Autoclaves	CPP				TEST	
4	Supply Clean Steam to twelve Autoclaves	CPP				TEST	
2.2	Process Requirements						
1	Clean Steam when condensed and RU per ICH Q7A.1	COP					TEST
2	Clean Steam condensation	COP					TEST
13	Clean Steam - Pressure	COP				TEST	
18	Degaser for Non Condensable Gases	CPP	TEST				
2.3	Process Control						
1	Automated Unattended Operation	NCOP	TEST				
3	CSG shall be controlled and monitored	NCOP	TEST				
4	Shutdown and Alarm based on Retention Time	COP			TEST		
2.4	Cleaning						
1	Equipment and piping shall be Cleaned and Passivated after FAT	CPP		DOC			
5	All surfaces contacted by product to be 316L SS 15-20 Ks EP Finish, or S.S. impregnated PTFE (Teflon)	CPP	TEST				
3	UL Listing	NCPP	DOC				
9	Instruments Calibrated under periodic program	NCPP			DOC		

Identifies required test functions
Identifies when testing will be executed
FAT, SAT, IQ, OQ, PQ